

REMARKS

Reconsideration and allowance of the present patent application based on the foregoing amendments and following remarks are respectfully requested.

By this Amendment, claim 12 has been amended. Claims 21, 22, 24, 27 and 28 have been cancelled. Claims 29-33 are newly added. Applicant submits that no new matter has been added.

After entry of this Amendment, claims 1-2, 4-18, 20, 25-26, and 29-33 will be pending in the patent application.

Claims 1, 2, 4-18, 21, and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,052,513 to Kaplan (hereinafter “Kaplan”) in view of U.S. Patent No. 5,874,074 to Smith (hereinafter “Smith”) and further in view U.S. Patent No. 5,993,836 to Castillo (hereinafter “Castillo”). Applicants respectfully traverse these rejections.

Claims 21 and 27 have been cancelled without prejudice or disclaimer, thus rendering moot the rejection of this claim.

Claim 1 discloses an oil-based formulation for desensitizing skin and hair follicles. Kaplan teaches away from suspending benzocaine in an oil. Kaplan specifically teaches dissolving benzocaine in an ester (such as diethyl sebacate), adding an emulsifier agent (a nonionic surfactant) to form a mixture, and adding the mixture to a water base solution. According to Kaplan, benzocaine is only very slightly soluble in water and attempts to solubilize benzocaine in water. Smith also discloses an oil-in-water emulsion formula for lotion, wherein emollients are melted together and then added with an acid to water.

First, with respect to claim 1, and as noted on page 3 of the Office Action, Kaplan does not teach the use of copolymers or plant oils. Smith is provided to allegedly fulfill this limitation. Applicant respectfully traverses this rejection as one of ordinary skill in the art would not have been motivated to modify the composition of Kaplan to employ the copolymers or floral oils of Smith to suspend benzocaine because Kaplan and Smith both focus on forming a water-based emulsion which can “carry” benzocaine or another topical anesthetic, not an oil-based composition that is “free of water” as provided in claim 1. Particularly, Smith discloses preferably using a barrier polymer that is soluble in water (see column 4, lines 11-13). Thus, even if the combination of Kaplan and Smith were deemed

proper, which Applicant does not concede, Kaplan and Smith would not provide all of the limitations of claim 1. As noted in the Office Action on page 3, neither Kaplan nor Smith nor their combination disclose anhydrous compositions. Rather, Kaplan discloses that the composition contains 30-90 percent water, and preferably 40-70 percent (see column 2, lines 31-35). Similarly, Smith discloses that the formulations contain 50-90 percent water (see column 6, lines 49-59).

Castillo is cited to allegedly fulfill the limitation “wherein the formulation is free of water” of claim 1. Castillo is noted as disclosing a topical anesthetic within a lipophilic base. On page 4 of the Office Action, the Examiner states that Castillo teaches “by using a lipophilic vehicle rather than an oil-in-water delivery system, the formulation is markedly improved,” and that it would have been obvious to modify the combination of Kaplan in view of Smith to employ an anhydrous lipophilic carrier. Applicant respectfully disagrees. Applicant contends it would not have been obvious to replace the 30-90 percent water in the compositions of Kaplan or Smith with a lipophilic base because the anesthetic formulation would not provide the same topical anesthetics or formulas as disclosed within the Kaplan and Smith references. Furthermore, the references cited cannot be fairly or functionally combined. In fact, the references themselves teach away from the proposed combination.

Thus, Kaplan, Smith, and Castillo do not disclose, suggest or teach the combination of the Applicant’s claims. Accordingly, Applicants respectfully request that the examiner withdraw the rejection of claim 1 based on the combination of Kaplan, Smith, and Castillo.

Claims 2 and 4-18 depend from claim 1 and therefore are submitted to be allowable for the reasons noted above, and for the features recited individually.

Claim 20 also discloses similar features as noted in claim 1; specifically, “wherein the composition is substantially free of water,” and, therefore, based on the arguments above, the rejections must be withdrawn and the claims allowed. Claims 25 and 26 depend from claim 20 and therefore are submitted to be allowable for the reasons noted above, and for the features recited individually.

Claims 20, 22, 24, and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,461,644 to Jackson et al. (“Jackson”) in view of Smith. Applicant respectfully traverses this rejection.

Claims 22 and 24 have been cancelled without prejudice or disclaimer, thus rendering moot the rejection of this claim.

The Office Action states that Jackson teaches anesthetizing polymer system that include the polymer PVC and a topical anesthetic that can be used as transdermal patches for providing an anesthetizing effect on the skin. With respect to claim 20, the Office Action states that while Jackson does not teach applying the anesthetizing polymer system to the scalp, one of ordinary skill would have been motivated to modify the anesthetizing method of Jackson to use it for hair removal from the scalp. Applicants respectfully traverse these rejections.

Jackson does not teach or suggest a method of desensitizing a scalp, particularly a scalp having hair, as recited by Applicants in claim 20. As discussed above, Jackson discloses applying the anesthetic polymer system through a transdermal patch. However, there is no suggestion that a transdermal patch, typically applied to the skin, could be effective when applied to the scalp. In fact, logic suggests that the hair on one's scalp would prevent, or at least substantially impair, the effectiveness of any type of transdermal or polymer drug delivery application on the scalp.

Moreover, Jackson does not teach a method of using a composition that contains a solubilizer for solubilizing the topical anesthetic or a plant extract oil. Instead, Jackson focuses on administering the anesthetic by incorporating it with a suitable wall polymer that meets three selection criteria. Jackson lists polyvinyl chloride and vinyl urethane copolymer as two of the preferred wall polymers (see paragraph 2, lines 24-59). There is no disclosure in Jackson relating to solubilizers or plant extract oils, nor is there any suggestion from the disclosure of Jackson that adding such components would facilitate the drug delivery polymer system described in Jackson.

It is acknowledged on page 5 of the Office Action that Jackson does not teach the use of at least one plant extract oil. Smith is provided to allegedly fulfill this limitation. However, there is no motivation to combine the patch or drug delivery system of Jackson with the lotion of Smith. Furthermore, even if Jackson and Smith were to be combined, which Applicant contends they cannot, the combination would still fail to provide the elements of claim 20. Particularly, as previously noted, Smith does not provide an oil-based composition noted in the claim. Rather, Smith discloses the use of a barrier polymer that is soluble in water. Thus, the combination of Jackson and Smith would lack the oil-based

composition, a solubilizer for solubilizing a topical anesthetic, and at least one plant extract oil as provided in the claim.

Accordingly, Applicants respectfully request that the examiner withdraw the rejection of claim 20 based on Jackson and Smith.

Claims 25 and 26 depend upon claim 20, and, therefore, are submitted to be allowable for the reasons above and for the features recited individually.

Claims 29-33 have been newly added and, *inter alia*, claim the use of at least one crystalline topical anesthetic, a solubilizer, at least one hydrophilic homopolymer, and at least one hydrophilic copolymer for desensitizing an area. None of the above references (Kaplan, Smith, Castillo, or Jackson), either alone or in combination, provide the limitations in claims 29-33. Thus, claims 29-33 should be allowed.

All rejections and objections having been addressed, it is respectfully submitted that the present application is in a condition for allowance, and a Notice to that effect is earnestly solicited. If the Examiner has any questions or suggestions that would facilitate the prosecution of the present application, she is encouraged to contact the undersigned at the below-listed telephone number.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP



Jack S. Barufka
Registration No. 37087
Tel. No.: (703) 770-7712

1650 Tysons Boulevard
McLean, VA 22102
703.770.7900 Telephone
703.770.7901 Facsimile